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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,180	02/12/2004	Marc Beauregard	15493-2US	3080
20988 7590 07/05/2007 OGILVY RENAULT LLP 1981 MCGILL COLLEGE AVENUE SUITE 1600 MONTREAL, QC H3A2Y3 CANADA			EXAMINER LIU, SUE XU	
			ART UNIT 1639	PAPER NUMBER
			MAIL DATE 07/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,180	Applicant(s) BEAUREGARD ET AL.	
	Examiner Sue Liu	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/12/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice of Non-Compliant Amdt.</u> |

DETAILED ACTION

Claim Status

1. Claim 7 has been canceled as filed on 4/12/07.
Claims 18-21 have been added as filed on 4/12/07.
Claims 1-3 and 10-21 are currently pending.
Claims 11-17 have been withdrawn as previously acknowledged;
Claims 1-3, 10 and 18-21 are being examined in this application.

Non-Compliant Claim Amendment

2. Applicants have amended the claims, however, the claim amendment is not compliant. Applicants are respectively directed to the attached "Notice of Non-compliant Amendment" for additional information.

Election/Restrictions

3. Applicant's election without traverse of Group I (Claims 1-10) in the reply filed on 10/27/2005 is as previously acknowledged. The newly added claims 18-21 are drawn to the Group I invention, and are thus examined in this application.

Priority

4. This application claims priority to provisional application 60/446,518 filed on 2/12/2003.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

5. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement Rejection

6. Claims 1-3, 7, 10 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1-propanol used in PCR reaction with certain thermo polymerases (Vent_r[®]) and DNA template (MB-1 His gene) to generate mutations in DNA with certain length in the presence of 1-propanol with certain concentration, does not reasonably provide enablement for Taq polymerase, all DNA template and propanol with concentrations beyond 8%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection over claims 1-3 and 10 is maintained for the reasons of record as set forth in the Office action. The rejection over claim 7 is moot due to applicant's cancellation of the said claim. The rejection over claims 18-21 is necessitated by applicant's amendment to the claims.

Discussion and Answer to Argument

7. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in *italic*):

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Applicants generally argue that the present invention in its full scope is enabled. (Reply, pp. 5-7). Applicants specifically discussed the cited Claveau reference. (Reply, pp. 6-7).

The instant claims are drawn to a genus of methods of PCR methods in the presence of propanol with intended use of inducing random mutation. The instant claimed method require the following main reagents:

- 1.) DNA templates;
- 2.) thermo-polymerases;
- 3.) 1-propanol; and
- 4.) other reaction reagents such as dNTP and primers.

The instant claims are broadly drawn to any DNA template, any *Thermus aquaticus* DNA polymerase, and any *Thermococcus litoralis* DNA polymerase mutant, etc.

The full scope of the present claims encompasses every possible combination of these ingredients for the claimed method.

As discussed in the previous Office action, due to the high unpredictability of PCR method in the presence of various amounts of 1-propanol, undue experimentation would be required to make and use the claimed invention in its full scope.

Applicants state the Claveau reference teaches "For Taq polymerase in the presence of 2.5% propanol, ..., resulting in a raw mutation frequency of 9.8×10^{-4} mutation/bp/PCR which is higher than the intrinsic Taq polymerase error rate by a factor of 3 to 4." (emphasis provided by applicants; Reply, p. 6, para 4), and thus the Taq polymerase in the presence of propanol is suitable for the purpose of the claimed invention.

Contrary to applicant's assertion, the Taq polymerase in the presence of 2.5% propanol is only one example that produced certain number of mutations. The reference's statement of "Considering the deletion-to-mutation ratio... considering it unsuitable for error-prone PCR" (emphasis added; p. 791, right col., para 3) cannot be ignored. As discussed above, the instant claims are broadly drawn to a genus of methods of using various Taq polymerases, in the presence of various concentrations of propanol, on various templates, to generate various mutations. The reference's statement indicates that at least for the purpose of generating high mutations rate (such as the one in error-prone PCR), the combination of Taq polymerase and at least 2.5% propanol does not work (i.e. "unsuitable"). Thus, at least for the embodiment of using Taq polymerase in the presence of 2.5% propanol for generating various mutations is highly unpredictable and requires further undue experimentation.

Applicants further dispute the citation on p. 793, left col., para 1, of the Claveau reference. Applicants state "since the purpose of the present invention is to increase the mutation rate of a DNA polymerase by addition of an alcohol, the invention works independently of the DNA template used." (Reply, p. 6, last para). First, the stated feature "increase the mutation rate..." is not a feature recited in the instant claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., increase the mutation rate of polymerase) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondly, contrary to applicant's assertion, the DNA template is not an independent element of the instant invention. In PCR reaction in general, a DNA template is a required element of the method, as evidenced by both the instant application and the Claveau reference. Applicants state "polymerization reaction... being possible on any DNA template" (Reply, p. 5, para 4). Applicant also state "it might be possible that some very long DNA templates might not work in an optimal way with the present invention, those very long DNA templates will easily be recognized by the skilled man in the art for not working with traditional polymerization techniques." (Reply, p. 6, last para). However, the instant claims are not drawn to the so-called "traditional polymerization techniques". As discussed above, the instant specification does not specifically define the term "template" to limit it to certain length. Thus, the instantly claimed method is drawn to "template" with any length. As stated by applicants, "long DNA templates" might not work with the presently claimed invention.

As discussed previously, the Claveau reference states "the longest amplicon obtained was 0.8kb" (p.793, left col., para 1). Thus, there is a limit to the length of the template as well as the PCR product that can be generated using the instant claimed method. In other words, the instant claimed method cannot be used to successfully generate any product using any template.

Applicants also state that the claim amendment to narrow the concentration range to 0.1-8% overcomes the unpredictability discussed in the Claveau reference. First, the critical concentration of 8% is only directed to the "Vent_r[®]" polymerase. The reference also states that the critical concentration for Taq polymerase is 2.5% (p. 791, Table 1). The instant claims (claim) reads on a PCR reaction with Taq polymerase in the presence of propanol that is beyond the 2.5% critical limit.

Applicants also state that the cancellation of the instant claim 7 overcomes the unpredictability discussed on p. 789, right col., of the Claveau reference. However, the instant claims are broadly drawn to a genus of methods of generating nucleic acids with mutations. The nucleic acids products are not limited to coding or non-coding sequences. Thus, the instant claims (Claim 1) are broadly interpreted to encompass generating nucleic acids that comprising both protein coding and non-coding sequences. As discussed in the previous Office action, the reference states: "increasing mutation rate to 10^{-1} error/bp/PCR or above... results in mutant libraries where no active genes are left" (emphasis added; p. 789, right col., right col.). Thus, it is highly unpredictable whether a given mutant nucleic acid generated from the instantly claimed method will results in a useful product. In other words, certain scope of the instantly claimed method is not enabled for making the desired products.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(Note: the instant claim numbers are in bold font.)

9. Claims 1-3, 10 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevet et al (Nucleic Acids Research. Vol. 23(16): 3343-3344. 1995), and Buchi (Buchi, J. "The Constitution-Effect Relationships from a New Viewpoint" Deutsche Apotheker-Zeitung 1966,

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pages 1695-1700 (1-29 for English translation)). The previous rejection over claims 1-3 and 10 is maintained for the reasons of record as set forth in the Office action. The rejection over claim 7 is moot due to applicant's cancellation of the said claim. The rejection over claims 18-21 is necessitated by applicant's amendment to the claims.

The instant claims recite a method for inducing a random mutation into a nucleic acid sequence comprising the steps of:

Providing a nucleic acid sequence for use as DNA template:

Submitting said DNA template to polymerization reaction with at least one DNA polymerase selected from the group consisting of a *Thermus aquaticus* DNA polymerase and a *Thermococcus litoralis* DNA polymerase mutant, in presence of 1-propanol in a concentration of between 0.1% to 8%.

Chevet et al, throughout the reference, teach methods adding various reagents to PCR reactions. The reference teaches using Vent polymerase (p. 3344, right col., para 2), DNA as template (p. 3343), and ethanol (p. 3344, right col., para 2), which reads on the method of **claims 1 and 3**. The reference also inherently teaches the concentration of ethanol to be between the critical ranges, because the reference teaches PCR reaction was carried out in the presence of ethanol and PCR products was formed (p. 3344, right col., para 2). As evidenced by Claveau et al (DNA Cell Biology. Vol. 23(11): 789-795; 2004; cited previously), "...increasing its [alcohol] concentration above 8% resulted in complete inhibition..." (p.793, left col., para 1). Thus, the ethanol concentration used by Chevet for the PCR reaction has to be within the workable range for the reaction to produce products (i.e. non-inhibition of the reaction).

The reference also teaches dNTP was used for the PCR reaction, which reads on the different nucleotides of **clm 10**. The reference also teaches the amplified DNA is encoding a surface protein (p. 3343, left col., para 2), which reads on **clm 7**.

Although the Chevet reference does not explicitly teach the reaction will induce random mutations as recited in the preamble of **clm 1**, in **clm 2, 7, and 10**, the “random mutation” is an inherent property of the Vent polymerase to induce random mutations including transversion/transition, as evidenced by Keohavong et al (PCR Methods and Applications, Vol 2, 288-292; 1993). Thus, the method using Vent polymerase would inherently produce random mutations as recited in **clms 1, 2, 7 and 10**.

The reference’s teaching also inherently teaches the range of mutation frequency rate as recited in **clms 18-20**, which is evidenced by Keohavong et al. Keohavong et al, teach mutation rate induced by Vent and Taq polymerases such as 2.7×10^{-4} error per base doubling (p. 289, col.3, para 3), which is within the range of “at least” $2-4 \times 10^{-6}$ of the instant claims.

The reference also teaches the sizes of the DNA templates used ranging from 593 bp to 15kbp (p.3343, col.1, para 2; Figure 1), which reads on the range of bp recited in **clm 21**.

The Chevet reference also does not explicitly teach the reaction is carried out in the presence of propanol (such as 0.1-8%).

However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute propanol (which has one more methylene group than ethanol) for ethanol to produce a homologous reaction mixture for PCR with favorable physicochemical properties (e.g., see MPEP §2144.09 “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to

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make a claimed compound, in the expectation that compound similar in structure will have similar properties.” In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). Here, Buchi indicates that homologous compounds will lead to “optimal” properties (e.g., see Buchi, section 4.4.3, “the study of homologous series is extremely important for the development of medicines with optimal properties ... lengthening the alkyl groups causes modification of important physical and chemical properties and chemical reactivity with the receptor, resulting in a gradual change in the activity and type of effect”). Thus, the “optimal” properties exhibited with the ethanol homolog, propanol can improve the PCR reaction through various physico-chemical interactions.

Discussion and Answer to Argument

10. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue “Chevet never even mentioned the word mutation in his reference”, and thus the reference does not anticipate the claimed invention. (Reply, pp. 7-8, bridging para).

First, the instant claim 1 recites the intended use of “inducing random mutation” in the preamble of the claim. Generally, the preamble reciting intended use of a claim is not afforded patentable weight. See MPEP 2111.02 II.

“If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations,

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then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”).

In this case, the recitation of “inducing random mutation into a nucleic acid” is construed as intended use of the claimed method. The instant claim (claim 1) language defines “a structurally complete invention” of a PCR reaction in the presence of propanol.

The instant claim 1 (the independent claim) recites a method with the following method steps:

- 1.) providing a DNA template;
- 2.) submitting the DNA template to a polymerization reaction (i.e. PCR) in the presence of propanol.

As discussed in the previous Office action and the instant office action, the above listed method steps are taught in the prior art (i.e. Chevet et al). Regardless whether the reference (Chevet et al) mentions the term “mutation”, the reference teaches all method steps recited in the claim, and thus anticipates the instant claims.

Furthermore, as discussed previously and above, PCR reaction using various thermo-polymerases in the presence or absence of alcohols (e.g. propanol) inherently has the property of inducing random mutations in the product DNA. Thus, the reference’s teaching anticipates the instant claimed method.

Applicants also argue that the cited reference does not teach “increase the intrinsic capacity to induce random mutations”. (Reply, p. 8; emphasis provided by applicants).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., “increase the intrinsic capacity to induce random mutations”) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also state the followings:

“in the office action dated December 19, 2005, pages 3 to 7, it was stated by the Examiner that the substitution of an alcohol for another cannot be considered obvious: ‘*It is not know how various alcohol molecules (such as propanol, ethanol, butanol, etc.) affect protein function and/or properties. In addition, the ultimate effect of alcohol on various polymerases (Vent, Taq, for examples) would be unpredictable.*’ The Examiner can not have it both ways, either the substitution of alcohol is obvious or is not !” [sic]

(Reply, p. 8)

Contrary to applicant's assertion, the quoted statement from the previous Office action (12/19/05) does not state that propanol is not obvious over ethanol. The above citation only discussed various alcohol in general, and does not offer a specific comparison between “ethanol” and “propanol”. As discussed in the previous office action and the instant office action, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute propanol (which has one more methylene group than ethanol) for ethanol to produce a homologous reaction mixture for PCR with favorable physicochemical properties, as

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evidenced by the cited references as well as supported by the cited case laws. Thus, the rejection is maintained for the reasons of record and the reasons stated above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
6/22/07

/Jon D. Epperson/
Primary Examiner, AU 1639

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

10/776,180

Examiner

Sue Liu

Applicant(s)

BEAUREGARD ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 12 April 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: See Continuation Sheet.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable

Telephone No.

Continuation of 4(e) Other: The text of the cancelled claim (i.e. Claim 7) is not deleted. See MPEP 714 II C: "A claim being canceled must be indicated as "canceled;" the text of the claim must not be presented".